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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/313,534	05/13/1999	ARTHUR G. ROMERO	4830.P-RE	4049

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EXAMINER
MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 09/27/2002 4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/313,534	Romero
Examiner	**Group Art Unit**
P Morris	1625

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on 4-5-02 + 7-9-02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above claim(s) 9-11 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8, 12 and 13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Reissue Applications

Claims 1-8, 12 and 13 are under consideration in this application.

Claims 9-11 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142 (b). Claim 13 has only been examined to the extent readable on the **elected** compounds, *i.e.*, R_3 and R_4 are joined to form an X-substituted-imidazolin-2-one. In addition, claim 13 recites new matter and is also drawn to non-elected compounds.

Claims 12 and 13 are rejected under 35 U.S.C. 251 for lack of defect in the original patent and lack of error in obtaining the original patent. Note MPEP 1450. The original patent shows an intent not to claim the newly presented invention. Hence, the invention cannot be added by reissue.

There is no evidence in the specification that applicants ever considered claims 12 and 13 to be their invention. The summary of the invention and detailed description of the invention in the patent recite that the invention relates to compounds of formula (I), compositions and use for the treatment of all anxiolytic disorders. The specification fails to recite that applicants ever considered the newly added compounds as their invention. Further, the specification is silent as to whether or not the newly added compounds treat any anxiolytic disorders.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12 and 13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. No evidence can be found in the specification that the instant compounds have any use at all.

The Supreme Court declined to express a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. Pats v. Manson, (USSC 1966) 383 US 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use-testing, reasoning the patent system is related to the world of commerce rather than the realm of philosophy ibid., 148 USPQ at 696.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

No enablement is shown for the treatment of all anxiolylic disorders. The tests set forth in column 4 of the specification is insufficient to support the compounds of claims 12 and 13 for the treatment of any and all anxiolylic disorders.

The disclosure provides no indication of whether the compounds treat any disease.

As pointed out in In re Schmidt, 377 F.2d 639, 153 USPQ 640 (CCPA 1967), lack of specificity about the medicinal properties and specific effects of claimed compounds is not outweighed by a detailed "boiler plate" recitation of conventional techniques limited to the manner in which the compounds may be formulated and administered. The disclosure must inform those skilled in the art how to use the invention, not merely invite them to find out for themselves how to use it. See also In re Moureu, 345 F.2d 519, 145 USPQ 452 (CCPA 1965).

The "how to use" requirements of 35 USC 112 are not met by disclosing only a pharmacological activity of the claimed compounds, if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Diedrich (CCPA 1963) 318 F2d 946, 138 USPQ 128; In re Gardner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138.

The Board of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of

human use and require proof thereof, when such use is a medical nature for the treatment of a serious disease. Ex parte Moore et al., (POBA 1960) 128 USPQ 8; In re Citron, (CCPA 1964 325 F.2d 248, 139 USPQ 516; In re Hartrop et al., (CCPA 1962) 311 F.2d 249, 135 USPQ 419.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support can be found for C_3 in the recited structure. The specification is silent as to whether the asymmetric carbon is in the R configuration.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claim 13 is rejected as being based upon a defective oath under 35 U.S.C. 251. See 37 CFR 1.175.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

The amendment filed July 9, 2002 proposes amendments to claim 13 that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Conclusion

Claims 1-8 are allowed.

Claims 12 and 13 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.

PATRICIA L. MORRIS
PRIMARY EXAMINER
GROUP 120

plm

September 26, 2002